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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/956,991	10/23/1997	JULIE R. KORENBERG	P-CE-2817	9464

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	30

DATE MAILED: 05/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/956,991	Applicant(s) KORENBERG, JULIE R.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,13-19,21-29 and 31-49* is/are pending in the application.

4a) Of the above claim(s) *11,13-19 and 21-29* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 31* is/are allowed.

6)☒ Claim(s) *32-44 and 46-49* is/are rejected.

7)☒ Claim(s) *45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 1997* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANT'S AMENDMENT

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 1/25/02 (Paper No. 29), is acknowledged.
Claims 1, 33-35 and 38 have been amended.
Claims 2-10, 12, 20 and 30 have been cancelled previously.
Claims 1, 11, 13-19, 21-29 and 31-49 are pending.

Claims 11, 13-19 and 21-29 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1 and 31-49 *are under consideration in the instant application.*

3. This Office Action will be in response to applicant's arguments, filed 1/25/02 (Paper No. 29). The rejections of record can be found in the previous Office Action (Paper No. 27).

It is noted that New Grounds of Rejection are set forth herein.

Applicant's arguments, filed 1/25/02, have been fully considered and are addressed below where appropriate.

4. The indicated allowability of claims 44-46 is withdrawn in view of the New Grounds of Rejection set forth herein.

5. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

6. The specification is objected to under 37 CFR 1.821(d) because the SEQ ID NOS are not disclosed in the specification adjacent referenced sequences. In particular it is noted that sequences are present in Figure 10 which lack sequence identifiers in the Brief Description of the Drawings. It appears that the sequences are fragments which can be indicated by reference to an existing SEQ ID NO:. However, if this is not the case, Applicant is reminded that the requirements of 37 CFR 1.821-1.825 must also be fulfilled. Appropriate correction is required.

7. Applicant should avoid the use of "novel" in the Abstract, as patents are presumed to be novel and unobvious.

8. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously provided.

It is noted that the Office is no longer holding drawing corrections in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in this Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

10. Claim 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

It is noted that instant claims 33, 34, 35 and 38, from which claim 47 depends, already limit the nucleic acid to a cDNA.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. The previous rejection of claims 33, 36, 37, 47 and 48 under 35 USC 112, second paragraph is withdrawn.

13. Claims 32, 40, 43 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 32, 40 and 43 each recite the limitation "containing the nucleic acid" of a preceding claim, where the preceding claim recites a vector. There is insufficient antecedent basis for this limitation in the claim.

It is suggested that Applicant amend the claims to either delete reference to the second claim in each set, or indicate that the isolated cell alternatively contains the vector of the relevant claim. For example, claim 32 would read -- An isolated cell containing the nucleic acid of claim 1 or the vector of claim 31. --

B) Claim 48 recites the limitation "the isolated nucleic acid ....which is RNA" and depends from claims 33, 34, 35 and 38 (in addition to claims 1 and 41). There is insufficient antecedent basis for this limitation in the claim with respect to claims 33-35 and 38, because claims 33-35 and 38 limit the nucleic acid to a cDNA.

It is suggested that Applicant delete the reference to claims 33-35 and 38 from claim 48.

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. The previous rejection of claims 33, 34, 36, 37, 47 and 48 under 35 USC 112, first paragraph is withdrawn in view of Applicant's amendment to the claims and arguments, filed 1/25/02.

16. Claims 34, 36-43 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons*:

A) Independent claim 34 and dependent claims 36-37 and 47-49 recite the limitation "that encodes amino acids 1069 to 1185 of SEQ ID NO:2".

Similarly, independent claim 38 and dependent claims 39-40 and 47-49 recite the limitation "encodes a polypeptide comprising ...984-1067, 1068-1185...of SEQ ID NO:2".

Applicant has addressed a similar rejection in the Remarks filed 3/9/01 (Paper No. 24). The Remarks pointed to Figure 2 in the context of the Sequence Listing for support for the various range limitations with respect to SEQ ID NO:2. While Figure 2 appears to support most of the fragments recited in instant claim 38, there does not appear to be support for the fragments of 1069-1185, 984-1067 or 1068-1185. It is noted that Figure 2 indicates that the FbN-3 domain of SEQ ID NO:2 begins at amino acid residue 1087 and ends at amino acid 1185. Amino acid 984 corresponds to the start of the second FbN domain.

However, amino acids 1067, 1068 and 1069 are contained *within* the second FbN domain; thus Figure 2 does not provide adequate written support for these positions since the second FbN domain ends with amino acid 1086 and FbN-3 begins with amino acid 1087.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

B) Independent claim 41 and dependent claims 42-43 and 47-49 recite the limitation "nucleotides 453-5169 of SEQ ID NO:1".

While there is clearly direction to nucleotides 453-5169 of SEQ ID NO:10 in the specification (e.g. at page 13, lines 32-33) and claims (e.g., claim 19) as filed, there does not appear to be adequate written support for "nucleotides 453-5169 of SEQ ID NO:1". The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter or amend the claims to remove the New Matter in the response to this Office Action.
Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

17. Claims 33-44 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Instant claims 33-35 (and dependent claims 36-37 and 47-49) are each drawn to a genus of nucleic acids which "hybridize under high stringency conditions" to various other nucleic acids disclosed in the specification.

Instant claim 38 (and dependent claims 39-40 and 47-49) is drawn to a genus of nucleic acids comprising nucleotide sequences encoding polypeptides comprising various "subsequences of SEQ ID NO:2".

Instant claim 41 (and dependent claims 42-43 and 47-49) is drawn to a genus of nucleic acid molecules comprising "*a* nucleotide sequence set forth in" various SEQ ID NOS disclosed in the specification, and therefore is drawn to any nucleic acid molecule comprising *any subsequence* of the various SEQ ID NOS.

Instant claim 44 (and dependent claim 46) is drawn to a genus of oligonucleotides *comprising any* 15 nucleotides of SEQ ID NO:7, SEQ ID NO:8 or a nucleic acid encoding SEQ ID NO:11. There is no restriction on the length of the oligonucleotide, thus permitting an extensive number of flanking nucleotides to be present without providing any description of their sequence.

Although the specification discloses that the polypeptides encoded by the nucleic acids of the invention would be expected to function as neural cell adhesion molecules based upon the presence of several Ig-like C2 domains and fibronectin domains and their expression in neural crest cells (e.g., on pages 9-11, 43-44 and 56-62); this functional activity is not required of the polypeptides or polypeptide fragments encoded by the nucleic acids recited by the instant claim language.

The possible variations in the structure of the polypeptides encoded by the instantly recited nucleic acids variants is extensive. Hybridization can occur when short stretches of identity are shared between two much larger nucleic acids. It is noted that the instant claims do not require hybridization over the full length of nucleic acid sequences. Similarly, subsequences require shared identity only over some defined (e.g., claims 38 and 44) or undefined (e.g., claim 41) minimal length. In each case additional unidentified sequence may be present, and may in fact be the dominant contributor to the structure of polypeptides encoded by such nucleic acids.

There does not appear to be any requirement that relevant, identifying characteristics of the instant nucleic acids must be shared among members of the genus recited. Neither are there testable functions recited for the polypeptides encoded by these variant nucleic acids sequences to provide some correlation between a particular structure and an associated, testable, function. Even with respect to the oligonucleotides recited, the presence of flanking sequence of undefined length and composition prohibits the at least 15 defined nucleotides from providing an adequate structural basis for the extensive genus of oligonucleotides encompassed by the claim. Thus one of skill in the art would not recognize Applicant to be in possession of the genus of nucleic acids and oligonucleotides encompassed by the instant claims.

Consequently, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicant is also directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

18. Claims 33-44 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acids of SEQ ID NO:1, SEQ ID NO:10, SEQ ID NOS 7-9, the oligonucleotides of SEQ ID NOS:5 and 6, and nucleic acids encoding SEQ ID NO:2 and SEQ ID NO:11; does not reasonably provide enablement for variants of the nucleic acids of SEQ ID NOS:1 and 10 which hybridize, subfragments comprising larger nucleotide sequences or which encode subfragments of the polypeptides of SEQ ID NO:2 or SEQ ID NO:11, or various oligonucleotides of unspecified length and undefined composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of SEQ ID NO:1 and SEQ ID NO:11 are transcribed in neural crest cells, that the gene responsible for these coding sequences is localized to a region of chromosome 21 associated with Down Syndrome (21q22.2-22.3), and that the encoded polypeptide is a neural cell adhesion molecule based upon its structural homology with other neural adhesion molecules and its expression pattern (e.g., on pages 9-11, 43-44 and 56-62).

However, as noted supra, the specification does not provide an adequate written description of nucleic acids which hybridize to the various SEQ ID NOS, nucleic acids which are subfragments comprising larger nucleotide sequences of undefined structure and function or which encode subfragments of the polypeptides of SEQ ID NO:2 or SEQ ID NO:11 which are not recited to be associated with any testable function. Consequently, the skilled artisan would not know how to make such nucleic acids.

In addition, the function of polypeptides encoded by these "variant" nucleic acid sequences would be highly unpredictable. The fact that two nucleic acid sequences will hybridize under high stringency conditions does not in and of itself require that the two sequences share any functional activity, nor does the presence of a shared subsequence.

Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2).

Thus the function of the polypeptides encoded by the instant nucleic acids that hybridize and nucleotide fragments is unpredictable.

Consequently, hybridization language in the absence of *a testable function* and limitations regarding both the hybridization conditions and the *sequence length over which the hybridization takes place*; does not allow the skilled artisan to make and use the hybridizing nucleic acids commensurate in scope with the instant claims without undue experimentation.

Similarly, it would require undue experimentation of the skilled artisan to determine which subsequences would have the unrecited function of the full length polypeptide, and in turn identify nucleic acid subsequences which encode these polypeptide subsequences.

Finally, even when the subsequences are derived from a defined sequence, as in instant claim 44, in the absence of direction as to a particular sequence length, it would require undue experimentation of the skilled artisan to select any particular oligonucleotide sequence from a SEQ ID NO: and to further determine what the appropriate flanking sequences should be.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the instantly recited nucleic acid sequences and still encode a polypeptide that maintains the functional properties of the polypeptide of SEQ ID NO:2 or SEQ ID NO:11 is unpredictable, as is the identity of which subsequences would encode a functional polypeptide; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. The previous rejection of claim 1 under 35 USC 102(a) as being anticipated by Korenberg et al. (PNAS, 1994; 91:4997-5001, IDS) is withdrawn. It is noted that Korenberg et al. does not appear to teach the isolation of a nucleic acid sequence encoding a polypeptide comprising SEQ ID NO:2 or 11 away from the pool of other chromosomal DNA fragments, nor specifically detect said nucleic acid.

21. The previous rejection of claims 33-35, 38 and 41 under 35 USC 102(a) as being anticipated by Korenberg et al. (PNAS, 1994; 91:4997-5001, IDS) is withdrawn for the reasons set forth supra.

22. The previous rejection of claims 35 and 48 under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. F13426, of record, is withdrawn since Applicant's arguments, filed 1/25/02 with respect to the rejection of record have been found convincing with respect to claims 35 and 48.

23. Claims 33-34, 36-37, 41-44 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. F13426, of record.

Applicant's arguments, filed 1/25/02, have been fully considered but have not been found convincing, essentially for the reasons of record in Paper No. 27.

The previous rejection may be found in Paper No. 27. Applicant acknowledges that F13426 is a 309 bp nucleic acid that overlaps with SEQ ID NO:1 from 5280-5589 (encoding amino acids 1610-1712 of SEQ ID NO:2) and that overlaps with SEQ ID NO:10 from 5133-5398 (encoding SEQ ID NO:11 from 1561-1571).

Applicant argues that although F13426 shares this region of overlap with SEQ ID NO:1 and SEQ ID NO:10, it nevertheless does not meet the instant claim limitations.

With respect to instant claim 33:
Applicant argues that the claim has been amended to recite a fragment of SEQ ID NO:11 which eliminates the region of overlap. However, it is noted that the instantly pending claim 33 does not recite a fragment of SEQ ID NO:11, and therefore the overlap persists and the limitations of instant claim 33 are still met by F13426.

With respect to instant claim 34:
Applicant argues that because F13426 overlaps with SEQ ID NO:1 only for those nucleotides of SEQ ID NO:1 encoding amino acids 1610-1712 of SEQ ID NO:2 that the limitations of instant claim 34 are not met by the teachings of the reference.

However, it is noted that the instant claim language recites a (cDNA) nucleotide sequence that hybridizes to second and third nucleic acids, but both the second and third nucleic acids each consist of the nucleotide sequence set forth in SEQ ID NO:1. The fact that the claim also recites that SEQ ID NO:1 encodes fragments of SEQ ID NO:2 is irrelevant to whether or not a nucleic acid would hybridize to SEQ ID NO:1. The recitation of encoding language does provide a further limitation when the entirety of SEQ ID NO:1 is recited. It is noted that the encoding language is not equivalent to reciting a fragment of SEQ ID NO:1. The teachings of F13426 still meet the instant claim limitations.

Dependent claims 36-37 and 47 are also still anticipated by the teachings of F13426 for the reasons set forth in Paper No. 27.

With respect to instant claim 41 (and dependent claims 42-43):
Claim 41 recites "a nucleotide sequence set forth in". In contrast to "*the* nucleotide sequence", the use of the indefinite article "a" reads on subsequences of the recited SEQ ID NOS:. Consequently, the teachings of F13426 also anticipate instant claim 41 and dependent claims 42-43 for the reasons set forth supra.

Similarly, instant claim 44 recites "an oligonucleotide comprising at least 15 nucleotides of a nucleotide sequence that encodes the polypeptide of SEQ ID NO:11". The sequence of F13426 also anticipates this claim because there is no requirement that the prior art sequence encode a polypeptide and as noted supra, F13426 overlaps at positions 5133-5398 of SEQ ID NO:10 which encodes amino acids 1561-1571 of SEQ ID NO:11.

Claim 46 is included because although the claim recites a "kit", the active ingredient of the kit is the oligonucleotide and the intended use carries no patentable weight to further distinguish the product.

The rejection is therefore maintained with respect to claims 33-34, 36-37 and 47, and claims 41-44 and 46 have now been included.

24. The previous rejection of claims 1, 31-43 and 49 under 35 USC 103(a) as being unpatentable over Korenberg et al. (PNAS, 1994; 91:4997-5001, IDS) in view of Gallatin et al. (US Pat. No. 5,525,487, IDS) is withdrawn for the reasons set forth supra.

25. Applicant's arguments, filed 1/25/02, with respect to the lack of motivation to combine the references in view of the partial sequence taught by GenBank Accession No. F13426 is found convincing. The previous rejection of claims 33-37 and 47-49 under 35 USC 103(a) as being unpatentable over GenBank Accession No. F13426 (of record) in view of Gallatin et al. (US Pat. No. 5,525,487, IDS) is withdrawn.

26. Claims 1 and 31 appear to be allowable as the prior art does not appear to teach or suggest an isolated nucleic acid encoding either SEQ ID NO:2 or SEQ ID NO:11. It is noted for examination purposes that the complement recited in section (b) of claim1 is considered to be the full length complement of the encoding nucleic acid.

27. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

28. Claim 32 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
May 2, 2002

Phillip Gambel
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5/1/02